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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,431	09/07/2000	Dominique P. Bridon	REDC-2201 USA	1545

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EXAMINER	
CHISM, BILLY D	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/657,431	BRIDON ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10-12 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-12 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to Applicants' paper filed 17 March 2004. Claims 1-6, 10-12 and 19-21 are currently pending and under consideration.

Withdrawal of Objections and Rejections

2. The rejections and/or objections made in the prior office action dated 17 December 2003, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 17 March 2004 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Rejections - 35 USC § 112

3. (Withdrawn) Rejections of claims 10-12 and 21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, are withdrawn as obviated by amended.

4. (Withdrawn) Rejection of claims 10-12 and 21 under 35 U.S.C. 112, first paragraph, because of lacking scope of enablement for the intended use whereby the composition is used for in vivo treatment of angiogenesis in humans is withdrawn, is withdrawn as obviated by Applicants' amendment or argument.

5. (Withdrawn) Rejections of claims 1-6, 10-12 and 19-21 under rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn as obviated by Applicants' amendment wherein the genus is now limited to comprising a peptide corresponding to a region of mammalian plasminogen.

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 19-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 19-21 of copending Application No. 09/623,543 (filed September 5, 2000). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-6 and 10-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 10-12 of copending Application No. 09/623,543 (filed September 5, 2000). Although the conflicting claims are not identical, they are not patentably distinct from each other because the modified

antiangiogenic kringle 5 peptide identified as SEQ ID NO: 8 is the same in both applications, hence intrinsically the method of manufacture would be the same and the resulting composition would retain the same properties.

10. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-5 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/41824 (13 November 1997/ IDS reference AM on sheet 1 of 3, February 2001). WO document 97/41824 discloses Applicants' SEQ ID NO: 8, see page 43, Example 5, line 12. This

disclosed amino acid is the same as Applicants' SEQ ID NO: 8 and is a modified antiangiogenic peptide comprising a reactive group (succinimidyl or maleimido) which reacts with amino groups, hydroxyl groups, or thiol groups on blood components to form stable covalent bond and reactive with a thiol group on a blood protein, see page 21, lines 13-38. This disclosed kringle 5 peptide, as well as derivatives and analogs thereof are comprised in a composition and administered for the treatment of both primary and metastatic solid tumors and compounds of several organ systems, see page 19, line 28-page 25, line 16. The WO document also discloses methods of manufacturing the anticipated composition including a kringle 5 peptide and derivatives and analogs thereof, see page 13, line 1-page 15, line 36 and page 43, Example 5. Given the disclosed composition and methods are the same as that claimed these peptides are capable of reacting with blood proteins and a thiol group on human serum albumin to form a covalent bond and is a medicament extending the *in vivo* half-life of kringle 5 peptide in a patient.

12. Claims 1-5, 10-11 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,057,122 (filed May 5, 1997/ IDS reference AD on sheet 2 of 3, February 2001). U.S. Patent number 6,057,122 teaches a kringle 5 peptide also known as a modified antiangiogenic peptide, see column 36, lines 26-30 and column 69, amino acid residues 83-93 of SEQ ID NO: 35. "Kringle 5 peptide fragments ...may be combined with pharmaceutically acceptable excipients or carriers to form therapeutic compositions" for the treatment of inhibition of angiogenic diseases, see Abstract; column 16, lines 46-column 17, line 57; column 19, lines 18-29; and column 20, line 63-column 21, line 5. Methods of manufacture of the disclosed modified antiangiogenic peptides are set forth in column 18, lines 5-column, 21, line 37.

Furthermore, the compounds of the disclosed invention may include a reactive group such as maleic acid or succinic acid, see column 18, lines 5-43. Given the disclosed composition and methods are the same as that claimed these peptides are capable of reacting with blood proteins and a thiol group on human serum albumin to form a covalent bond and is a medicament extending the *in vivo* half-life of kringle 5 peptide in a patient.

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

***

B. Dell Chism

CHRISTOPHER R. TATE
PRIMARY EXAMINER